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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,824	03/23/2005	Alain Rambach	37991-0035	6976

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EXAMINER	
PETERSEN, CLARK D	
ART UNIT	**PAPER NUMBER**
1657	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,824	RAMBACH ET AL.	
	Examiner	Art Unit	
	Clark D. Petersen	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,7,8,10-12 and 14-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,7,8,10-12, and 14-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to the amendment, filed 25 October 2006, in which claims 2, 4-6, 9, and 13 were canceled and claims 1, 3 and 15 were amended.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

All objections and rejections not repeated in the instant Action have been withdrawn due to Applicant's response to the previous Action.

Because Examiner is presenting new grounds of rejection in this Office Action, the Action is NON-FINAL.

Claim Objections

Claims 1 and 14 are objected to because of the following informalities: "meticillin" is a misspelling. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 now depends from canceled claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3, 7, 8, and 14-16 are provisionally rejected on the ground of nonstatutory double patenting over claims 1-12 of copending Application No. 10/753417 (US PGPub # US2004/0235012 A1). This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: Both applications share Alain Rambach as inventor. Claim 8 of Application No. 10/753417 recites all the limitations of Claims 1, 3, 7, 8 and 14-16 of the instant application. Claim 8 recites a method of detecting a methicillin-resistant *Staphylococcus aureus*

by culturing on a chromogenic medium comprising the chromogens recited in instant claims 3, 7, and 16 and also comprising an antibiotic such as cefamandole, cefoxitin, cefotetan, or moxalactam. Claims 9-12 of Application No. 10/753417 also recite these limitations.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Response to Arguments - 35 USC § 102

Applicants argue that Grant nowhere suggests that his invention is applicable to selection of *S. aureus* in any form. Based on Applicants' amendments and arguments, the rejection of instant claims 1, 8, 10, and 14 under 35 USC 102(b) as being anticipated by Grant is withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 10, 11, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Merlino et al (J Clin Microbiol, June 2000) in view of Felten (J Clin Microbiol, Aug 2002).

This is a new rejection.

The teachings of Merlino et al are discussed above.

Merlino does not teach the use of the claimed cephalosporin antibiotics as selective agents in a chromogenic medium.

Felten et al teach that it is difficult on occasion to discern class 1 MRSA *S. aureus* from methicillin-susceptible *S. aureus* with standard oxacillin-resistance tests (see Abstract and Introduction, for example). They report that testing a MRSA type 1 strain with cefoxitin or moxalactam led to 100% identification of MRSA type 1 strains as being methicillin-resistant, which is an improvement over the reliability of oxacillin testing, as taught be Merlino et al (see Felten et al, p. 2768, Table 1 and Results). In particular, Felten et al teach that antibiotic susceptibility tests can be carried out in medium containing no salt or 2% salt (see p. 2767, col. 1, first paragraph for example). There is no mention of adding salt in medium containing moxalactam (see p. 2767, col. 2, sections (ii) to (iv), for example). Moxalactam, for example, was added to MHA medium before solidification at a concentration of 0.5 to 32 mg/L (see p. 2767, col. 2, section (iv).

A person of ordinary skill in the art at the time the invention was made would have been motivated to test MRSA resistance among *S. aureus* strains in a method taught by Merlino et al using antibiotic resistance testing taught by Felten et al, because Merlino et al teach that one can distinguish reliably distinguish *S. aureus* from other strains of *Staphylococcus* using a chromogenic reagent, and Felten et al teach that one can more reliably detect low-level methicillin resistance using later generation cephalosporins like cefoxitin and moxalactam.

Hence, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to test for methicillin resistant *S. aureus* strains by testing antibiotic

resistance with moxalactam or cefoxitin, and ensure proper species recognition with a chromogenic reagent when attempting to characterize clinical bacterial isolates.

Claims 1, 10-12, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Merlino (J Clin Microbiol, June 2000) in view of Felten (J Clin Microbiol, Aug 2002) and in view of Boggs et al (US Patent # 5,883,074, issued 16 March 1999).

This is a new rejection.

The teachings of Merlino et al and Felton et al are discussed above and applied as before.

Merlino et al and Felten et al do not expressly teach the use of cefamandole and cefotetan in a method of detecting MRSA bacteria.

Boggs et al teach that MRSA *S. aureus* develop resistance to numerous antibiotics (see Summary of the Invention, col. 1 line 48 to col 2 line 40, for example). Boggs et al teach that one must selectively grow MRSA *S. aureus* by including an antibiotic; this antibiotic can be cefamandole, cefoxitin, or cefotetan (see col. 4 line 56 to col. 5 line 13; see col. 6, lines 13-25, for example).

A person of ordinary skill in the art at the time the invention was made would have been motivated to include cefamandole, cefoxitin, or cefotetan because Boggs et al teach that MRSA *S. aureus* are often selectively resistant to these drugs.

Hence, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to test for MRSA resistance in *S. aureus* using a S. aureus-selective chromogenic medium and cefamandole, cefoxitin, or cefotetan as selective antibiotics.

Claims 1, 10-12, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Merlino (J Clin Microbiol, June 2000) in view of Felten (J Clin Microbiol, Aug 2002) and in view of Dorso et al (US Patent # 6,221,859, issued 24 April 2001).

This is a new rejection.

The teachings of Merlino et al and Felton et al are discussed above and applied as before.

Merlino et al and Felten et al do not expressly teach the use of cefmetazole in a method of detecting MRSA bacteria.

Dorso et al teach a method of treating antibiotic resistant *S. aureus*, among other types of pathogenic bacteria (see Abstract, see Summary of the Invention, col. 1 line 59 to col. 2, line 5, for example). They teach that cefmetazole is among the antibiotics that are losing efficacy against pathogenic bacteria, and must be combined with other compounds to enhance treatment (see col. 8, line 63 to col. 9, line 10, for example).

A person of ordinary skill in the art at the time the invention was made would have been motivated to include cefmetazole in a selective medium for detecting resistant *S. aureus*, because Dorso et al teach that cefmetazole is a compound that is subject to bacterial resistance, and Felten et al and Merlino et al teach a method of detecting *S. aureus* with resistance to a given antibiotic.

Hence, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to test *S. aureus* resistance against cefmetazole by culturing on a medium containing cefmetazole and a chromogenic reagent.

Claims 1, 10-12, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Merlino (J Clin Microbiol, June 2000) in view of Felten (J Clin Microbiol, Aug 2002) and in view of Hanaki (US Patent # 6,294,527, issued 25 Sep 2001).

This is a new rejection.

The teachings of Merlino et al and Felton et al are discussed above and applied as before.

Merlino et al and Felten et al do not expressly teach the use of flomoxef in a method of detecting MRSA bacteria.

Hanaki et al use flomoxef-doped plates as a control for testing other compounds against *S. aureus* bacteria. Use of flomoxef as a control distinctly shows its use for characterizing MRSA S. aureus versus non-resistant *S. aureus*. Flomoxef has no effectiveness against MRSA bacteria, but is extremely effective against non-resistant bacteria (see col. 11 line 52 to col. 12 line 35; see Table 1, col. 12, as examples).

A person of ordinary skill in the art at the time the invention was made would have been motivated to include flomoxef in a selective medium for detecting resistant *S. aureus*, because Hanaki et al teach that flomoxef is a compound that is subject to bacterial resistance, and Felten et al and Merlino et al teach a method of detecting *S. aureus* with resistance to a given antibiotic.

Hence, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to test whether *S. aureus* has MRSA characteristics by culturing on a medium containing flomoxef and a chromogenic reagent.

Claims 1, 3, 7, 8, 10-12, and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Merlino et al (J Clin Microbiol, June 2000) in view of Felten et al (J Clin

Microbiol, Aug 2002) and in view of Rambach (US Patent # 6,548,268, issued 15 Apr 2003, claiming priority to 9 Mar 2000).

This is a new rejection.

The teachings of Merlino et al and Felten et al are discussed above and applied as before.

Merlino et al and Felten et al do not expressly teach the use of 5-bromo-4-chloro-3-indoxyl glucoside, 5-bromo-6-chloro-3-indoxyl phosphate, or 5-bromo-4-chloro-3-indoxyl glucuronide as chromogenic reagents.

Rambach teaches that these reagents are effective chromogenic reagents for detecting *S. aureus*. Rambach teaches that each of the above chromogenic dyes can be used to detect growth of *S. aureus*, which generates a different color in the presence of the substrate than other *Staphylococcus* species in particular, and other bacterial species generally (see column 2, lines 12-17; see column 2 lines 32-39, as examples). Additionally Rambach expressly endorses adding two or all three chromogenic substrates together for optimal detection of *S. aureus* (see lines 32-39, for example). Specifically, Rambach teaches that indoxyl phosphate or glucoside should be used as a first chromogen; the selectivity is enhanced if indoxyl glucuronide is added as well, reading on instant claims 3, 7, and 8 (see col. 2, lines 12-39, for example). Additionally Rambach teaches that indoxyl glucoside can be included, reading on claim 16. These chromogens can be included at a concentration of 0.05 g/l (see col. 2, lines 55-60, for example).

A person of ordinary skill in the art at the time the invention was made would have been motivated to use the chromogenic substrates taught by Rambach et al in a method of detecting MRSA *S. aureus* taught by Merlino et al and Felten et al, because Merlino et al teach that chromogenic substrates can be used to detect MRSA *S. aureus*, Felten et al teach that cefoxitin

and moxalactam can be used to detect low-resistance *S. aureus*, and because Rambach teaches that *S. aureus* can be specifically identified by growing on the chromogenic substrates identified in his patent publication.

Hence, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to identify MRSA *S. aureus* as taught by Merlino et al and Felten et al using the chromogenic substrates taught by Rambach.

Response to Arguments - 35 USC § 103

Applicants have traversed the rejection of claims 1, 2 and 15 under 35 USC 103(a) as being unpatentable over Grant in view of Merlino. Based on applicants arguments and amendments to the claims, this rejection is withdrawn.

However Examiner is relying on Merlino et al for new grounds of rejection in this Office Action.

Applicants argue that the teachings of Merlino et al cannot be applied because Merlino et al teach a chromogenic medium comprising methicillin/oxacillin that will not detect all forms of antibiotic resistant *S. aureus*, and cites the Discussion on p. 2380 for support. Examiner agrees with this contention, however detection of all forms of antibiotic resistant *S. aureus* is not found in the scope of the instant claims. Claim 14, for example requires only that unspecified microorganisms be *methicillin* resistant. The teachings of Merlino et al anticipate the scope of this claim, as discussed above.

Furthermore Merlino can be applied in support of a rejection of instant claims under 35 USC 103(a). Again, Examiner agrees that the method taught by Merlino et al does not detect

weaker forms of MRSA resistance, however that is not the scope of the instant claims. Interpreted broadly, the claims could read on any form of MRSA resistant *S. aureus*, whether it is resistant to the most stringent selection or not. In any case the teachings of Felten et al can be applied in detecting weaker forms for MRSA resistance.

Applicants have traversed the rejection of claims 1, 3, 7, 8, 12, and 15 under 35 USC 103(a). Based on Applicants' amendments and arguments, this rejection is withdrawn.

However Examiner is relying on Rambach for new grounds of rejection in this Office Action.

Applicants argue that the teachings of Rambach cannot be applied to the instant set of claims because Rambach teaches that it is necessary to have deferoxamine in the medium. However Rambach teaches that deferoxamine is included to select against *S. epidermis* (see col. 2, lines 27-32, for example); therefore, deferoxamine is a selective agent, not a chromogenic agent. Because of the inclusion of desferoxamine in the teachings of Rambach, the claims are narrower than the scope of the chromogenic agents in the instant application, and therefore would render obvious the broader use of chromogenic agents taught in the instant claims.

Applicants have traversed the rejection of claim 1 under 35 USC 103(a) as being unpatentable over Grant in view of Vouillamoz et al. Based on Applicants' amendments and arguments, this rejection is withdrawn.

Applicants have traversed the rejection of claims 1, 5, 6, 9, and 11 under 35 USC 103(a) as being unpatentable over Grant in view of Aratika et al. Based on Applicants' amendments and arguments, this rejection is withdrawn.

Conclusion

No claims are allowed.

Because Examiner has introduced new grounds for rejection, this action is NOT FINAL.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clark D. Petersen whose telephone number is (571)272-5358. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571)272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JON WEBER
SUPERVISORY PATENT EXAMINER